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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,854	02/07/2005	Soon Keun Lee	930086-2007	4420
7590	05/23/2008		EXAMINER	
Ronald R Santucci Frommer Lawrence & Haug 745 Fifth Avenue New York, NY 10151			WINSTON, RANDALL O	
			ART UNIT	PAPER NUMBER
			1655	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/523,854	LEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	RANDALL WINSTON	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 February 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-5, 7 and 10-21 is/are pending in the application.

4a) Of the above claim(s) 5 and 13-21 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4, 7 and 10-12 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

    1. Certified copies of the priority documents have been received.

    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Acknowledgement is made of receipt and entry of the response to the amendment filed on 02/06/2008.

Examiner acknowledges that the 35 USC 112, first and second paragraph rejections, have been overcome by Applicant's amendment.

Examiner acknowledges that claims 5 and 13-14 are withdrawn from consideration and new claims 15-21 are withdrawn for the reasons stated below.

Examiner also acknowledges that claims 6 and 8-9 are cancelled.

**ELECTION BY ORGINAL PRESENTATION**

Claims 15-21 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally presented claims (i.e. claims 1-4, 7 and 10-12) were examined over the art insofar as it reads on composition. However, claims 15-21 are now drawn to a method of using which is different and distinct from the originally presented and examined composition invention. Since applicant has received an action on the merits for the originally presented invention of a composition, this invention has been constructively elected by original presented invention for the prosecution on the merits. Accordingly, claims 15-21 are withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP 821.03.

Therefore, claims 1-4, 7 and 10-12 have been examined on the merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto (JP 409143087 A, see abstract) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a topical formulation comprising an extract obtained from the elected species from the Markush Group of a *Canavalia gladiata*.

Yamamoto anticipates the claimed invention because Yamamoto teaches a topical formulation comprising an extract obtained from the elected species of *Canavalia gladiata* (see, e.g. abstract). Therefore, the reference is deemed to anticipate the claimed invention.

Please note, the intended use of the above claimed composition (i.e. to treat acne) does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Applicant's argument has been carefully considered but it is not deemed persuasive. Applicant argues that claim 1 is directed to a topical formulation for treating acne, which Yamamoto are related to a preparation for improving skin roughness, therefore, Yamamoto does not anticipate the claim invention.

Although Applicant argue that claim 1 is directed to a topical formulation for treating acne, which Yamamoto are related to a preparation for improving skin roughness, Applicant argument is not found persuasive because the intended use of the above claimed composition (i.e. to treat acne) does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1-4, 7 and 10-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wakasaya (JP 2001089346 A of Derwent Acc NO 2001-324724, see abstract) in view of Sugihara et al. (JP 355127317 A, see abstract)

and Basu et al. (US 20020025348) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims topical formulation comprising extracts obtained from the elected species of *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis* in various amounts.

Wakasaya teaches a formulation comprising an extract obtained from the elected species of *Canavalia gladiata* (i.e. sword beans)(see, e.g. abstract) administered to a subject to treat inflammation disorders. Wakasaya does not expressly teach the combination of *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis* administered to a subject to treat inflammation disorders (see, e.g. abstract).

Sugihara beneficially teaches *Biota orientalis* extracts externally administered to a subject treats inflammation disorders (see, e.g. abstract).

Basu beneficially teaches *Coptis chinensis* extracts externally administered to a subject treats inflammation disorders (see, e.g. entire patent including abstract, paragraph 21 and claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Wakasaya's formulation to include the claimed active ingredients of *Biota orientalis* and *Coptis chinensis* as taught by Sugihara and Basu within Wakasaya's formulation teachings because the above combined reference as a whole would create the claimed invention of claims a topical formulation comprising extracts obtained from the elected species of *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis* to treat

inflammation disorders. Moreover, as discussed in MPEP Section 2114.06, “it is *prima facie* obvious to combine two or more compositions each of which is taught

by the prior art to be useful for the same purpose (i.e. to treat inflammation disorders), in order to form a third composition to be used for the same purpose...”

Furthermore, the adjustment of other conventional working conditions (e.g. determining suitable amounts/ranges of each active ingredient within the claimed formulation and the substitution of one form of the formulation for another), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note, the intended use of the above claimed composition (i.e. to treat acne) does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues there is no motivation to combine Wakasaya with the other cited references in order to arrive at the invention because as noted these claims relate to the treatment of acne.

Although Applicant argues that argues there is no motivation to combine Wakasaya with the other cited references in order to arrive at the invention because as noted these claims relate to the treatment of acne, Applicant argument is not found persuasive because as discussed in MPEP Section 2114.06, "it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat inflammation disorders), in order to form a third composition to used for the same purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Wakasaya's formulation to include the claimed active ingredients of *Biota orientalis* and *Coptis chinensis* as taught by Sugihara and Basu within Wakasaya's formulation teachings because the above combined reference as a whole would create the claimed invention of claims a topical formulation comprising extracts obtained from the elected species of *Canavalia gladiata*, *Biota orientalis* and *Coptis chinensis* to treat inflammation disorders. Please note that the intended use of the above claimed composition (i.e. to treat acne) does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the

instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655